

Exhibit D



2016 NFL PLAYERS & HPN HIGH PERFORMANCE NEUROFEEDBACK STUDY

EVALUATING THE EFFECTIVENESS OF ULTRA LOW POWER, PULSED ELECTRIC CURRENT EEG BIOFEEDBACK IN TREATING SYMPTOMS OF REPETITIVE TRAUMATIC BRAIN INJURY IN RETIRED NFL ATHLETES

A Compendium of information previously presented at the International Society for Neurofeedback and Research (ISNR) Annual Meeting, 2014, Association of Applied Psychophysiology and Biofeedback (AAPB) Annual Meeting, 2016, and ISNR Annual Meeting, 2016 by George Rozelle, Ph.D., BCN, Senior Fellow, Diplomate in QEEG and Neurotherapy

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ABSTRACT

In 2014 clinical trials were conducted at two sites in Florida to investigate the effects of ultra-low power pulsed electrical EEG biofeedback for the treatment of symptoms related to repetitive traumatic brain injury (rTBI) in former professional football players. The neurofeedback approach chosen was passive neuromodulation of the EEG signal. This is different from operant conditioning approaches in that it is not guided by a QEEG and does not require the subject to be engaged in the feedback signal. The method involves securing two active electrodes to a subject's scalp, two reference electrodes to the ears or mastoid, and one ground placed on the back of the neck, just above the seventh cervical vertebra. The EEG signals are recorded continuously, amplified via differential amplifiers and digitized by Analog-to-Digital conversion. The dominant frequency between 1 and 12.5 Hz is continuously calculated and a pulsed electrical signal is fed back with a time domain distortion. The signals are thus input directly to the brain and nervous system, bypassing the normal systems of perception. Five retired NFL players completed twenty neurofeedback sessions over a three-month period. Pretesting, post testing, and follow-up testing suggests that this is a viable treatment approach.

BACKGROUND

Chronic traumatic encephalopathy (CTE) is a neurodegenerative syndrome that has been linked to serious psychiatric symptoms, including depression, aggression, and suicidal behavior. This review critically examines the extant research on the behavioral manifestations of rTBI on individuals who are considered at risk for CTE. There is growing evidence of a causal relationship between rTBI and CTE and the onset of behavioral health problems.



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The subjects of this study consisted of former NFL players who have been diagnosed with either Mild or Major Neurodegenerative Disorder as defined by the DSM-V. All subjects had received an indeterminable number of football related concussions and sub-concussive hits. Evidence suggests that rTBI may lead to Mild and Major Cognitive Disorder as well as CTE (Stern, Daneshvar, & Baugh, 2013). However, since there is no current published and accepted criteria diagnosing CTE in a living person, one may make the assumption, based on the high percentage of NFL players diagnosed post-mortem, that some of this population could have "probable or possible CTE" (Montenigro, 2014). Because of the enormous human and financial cost of TBI and rTBI it is imperative to systematically research any new treatment approaches which show the potential to slow or reverse the effects of rTBI. With a CDC estimated 1.6 to 3.8 million concussions each year (US Department of Health and Human Services: Centers for Disease Control and Prevention), it is proposed that intervention earlier in life may reduce the risk of rTBI evolving into Mild or Major Neurocognitive Disorder or even CTE.

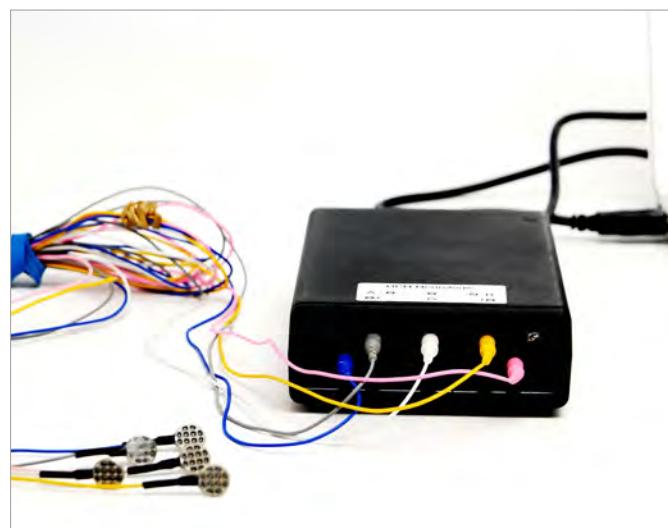
OBJECTIVE

The objective of this study is to determine the short-term and long-term efficacy of this neurofeedback approach in the reduction of symptoms related to rTBI and enhancement of cognitive function. Evaluation of each subject before, during, after and in follow up assessments provided several measures of response to treatment. Based upon clinical trials findings, a larger independent multi-site study is currently underway. The multi-site evaluation of the defined treatment protocol creates a powerful way to study the efficacy of this neurofeedback approach in this high-risk population. In addition, it will provide specific quantitative measurements of individual improvement over the course of treatment and whether that improvement is retained over time. The recent deaths of several high-profile athletes have resulted in significant public and scientific interest in the long-term effects of mTBI and chronic traumatic encephalopathy (CTE), a progressive neurodegenerative disease linked to repetitive brain trauma.

METHOD

Equipment: HPN Neurofeedback Device:

The study device was the J&J I-330 C2+2-CHANNEL EEG Amplifier, with modifications for Mind-Brain Training Institute, running Physio lab USE3 software. The device is registered with the FDA under a 510 (k) exemption. The specific form of Neurofeedback being evaluated, Pulsed, Ultra Low Power, Electric Current EEG Biofeedback (HPN) has shown impressive results in a recent pilot study with multiply concussed former NFL players.





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A method and system for retraining brainwave patterns to promote higher and more adaptive functioning using ultra low power direct electrical stimulation feedback is herein described. Relatively small Electroencephalographic (EEG) signals are acquired by electrically connecting 2 or more leads to the scalp of a client. Each channel to be acquired requires an Active (+) lead, a Reference (-) lead and a Common lead. The common lead may be connected almost anywhere on the body that is convenient, but preferable sites include the back of the neck, the ear, the face and the scalp. For multi-channel systems, the common lead is shared, and more than one channel may share a "linked" reference (-) lead, depending on the configuration desired. These leads conduct EEG signals to a "front-end", comprising one or more instrumentation amplifiers, one for each channel, or signal, to be acquired. These amplifiers typically have high common-mode rejection (CMMR) ratios, so that very little more than difference signals are amplified. The front end optionally may be followed by one or more stages of amplification. The amplified signal is then fed to an analogue-to-digital converter (ADC), typically comprising a sample- and-hold circuit, followed by the digitizing circuit. The output of the ADC is typically fed to a digital processor as a sequence of values, each representing a sample of the input signal at a specific point in time. Within the digital processor are algorithms for further processing and analyzing the digitized EEG signal, typically to extract one or more characteristics of the EEG signal for further processing or analysis, for example by use of digital filters and/or Fast Fourier Transforms (FFTs). These techniques are all well known in the current art, and are generally summarized as "signal acquisition and analysis".

In one embodiment of the present invention, at least one EEG input channel is selected from which to derive feedback, either through manual selection, for example, via computer screen, keyboard and/or pointer device, or, as one possible alternative, through a prepared program or script specifying various parameters, including which channel or channels are selected for each time period.

A digital-domain representation is thus created of one or more selected EEG signals. A time-domain "distortion", that is, either faster or slower, of the resultant digital-domain representation is then accomplished by one of any of a number of means well known in the art, for example using a Fast Fourier Transform (FFT) to extract a peak, dominant, or modal frequency, and then regenerating a faster or slower version of the extracted frequency by means of a waveform generator. Another time-domain distortion means could be re-sampling the digitized waveform to yield a waveform of similar shape, but whose frequency would be sped up or slowed down by the ratio of input to output sample frequencies. The time-domain distortion signal thus created is converted directly or indirectly to a series of very short pulses whose spacing would represent the zero-crossings of one or more of the newly derived time- distorted frequencies. These pulses are further differentiated and coupled back onto one or more pairs of input leads, (both Active (+) and Reference (-) with respect to Common), which couplers may optionally may be provided with resonant circuits utilizing inductance and capacitance to induce an oscillation on the leading and possibly trailing edges of the pulses to further improve skin conduction. The resulting signal contains extremely low power, that is, "ultra-low power", but according to recent experience and current understanding, would activate one or more of the mentioned nervous systems of either humans or other vertebrates, with the intent to encourage nervous system normalization while minimizing the likelihood of undesirable reactions. The signal is so low in power that it is imperceptible directly, but on rare occasion the client may be aware of a sensation caused by the changes being produced, for example, normalized blood flow, nerve function, or autonomic balance. It requires no effort on the part of the client, and may therefore be useful in situations in which the client is unconscious or otherwise incapable of conscious cooperation.



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It may also be desirable and beneficial to incorporate one or more additional, essentially fixed frequency signal components which are similarly differentiated and shaped as previously described.

The described system has been utilized effectively in human trials, and some other vertebrate trials, including horses and dogs. The robust results have profound implications in the restoration of nervous system balance and function in both humans and animals, particularly following brain injury.

Subjects: Former NFL football players

HPN was evaluated for efficacy in treating symptoms of rTBI in retired NFL players. Before, during and after subjective and objective measurements were taken, with follow up measurements at 3 months and 1 & 2 years to evaluate the long-term effects of the treatment. Each player received 20 sessions of the defined HPN protocol.

Inclusion Criteria:

- Played in NFL for at least one year
- Endorsed at least 4 items on the Rivermead as moderate to severe symptoms.
- Agreed to commit to pre and post testing and 20 treatment sessions.

Exclusion Criteria:

- Active alcohol or drug abuse problem
- Overt symptoms of advanced neurodegenerative disease, i.e. chronic traumatic encephalopathy (CTE).
- CNS impairment for reasons other than trauma such as stroke and/or prior neurosurgery.
- Recent suicide attempts or having a specific plan to do so.

Treatment of Subjects:

Subjects were screened for any contraindications such as seizures before applying any intervention.

The treatment was explained to them in detail. All of their questions were answered. Due to the urgency of their condition wait list controls were not employed. There were no sham treatments.

Identity and privacy of the subjects was protected using HIPAA rules. In the research database the results of a given intervention record, the medical records of the subject or any other data with their name was redacted before being stored in the research database. Demographics stored were total years playing football (professional and college), and age. At all times subjects will be treated with respect and courtesy.

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In utilizing HPN technology, micro voltages in the form of pulsed electrical frequencies were introduced to the brain in such low levels (approximately 3 picowatts) that an AA battery would be a hundred thousand times greater current. The micro voltages however are introduced at a frequency differential that will tend to provoke the brain to let go of the non-optimal brain patterns. Hence the approach is very safe with minimal risk of side effects. These electrical pulses produce a bi-directional flow between the scalp electrodes and the ground located just above C7 on the back of the neck. Theoretically if the deep brain structures are either involved or interfering with executive function this will also affect those areas as well.

Procedures:

- Five Players completed Pre and Post QEEGs, Rivermead Concussion Scale, Impact, King-Devick and Sway Balance
- Five Players completed 20 HPN sessions provided twice weekly over approximately ten weeks. Those players showed improvement on all measures except the Impact.
- Three out-of-state players completed week-long intensives with twice daily treatments (all improved, but not included in study)
- One of the week-long intensives: HPN + LORETA Z-Score Neurofeedback (Brain Surfer)
- Two players dropped out
- Four players started treatment at the Sarasota site and finished at the Palm Harbor site.

Protocol:

- Basic Gentle
- Set 10 Hz offset from dominant frequency measured on Channel A
- Dominant frequency determined from a range of 1-12.5 Hz.
- Fifteen 30-second intervals.
- Homologous pairs front to back to front, then midline and selected sites.

QEEG MEASURES

Brain electrical activity was recorded from a 19-channel Electro-Cap, referenced to linked ears, on a Brain Master Discovery 24-E QEEG Instrument in accordance with the 10-20 International Electrode Placement System. Electrode impedance was reduced to less than 5.0 K ohms at each placement. Sampling rate =256. No activation procedures were used.

The raw recording was digitized for data storage and analysis, manually edited to reduce artifact (eye movement, EMG, body movement etc.) and subjected to quantitative spectral analysis. Recording conditions were awake and alert, eyes open and eyes closed. The raw data were examined in a variety of montages. The results of spectral analysis were displayed in color-coded topographic maps, and statistical reports. The QEEG was based upon at least sixty seconds of edited raw EEG data for each testing condition.



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DATA BASE COMPARISONS

An analysis of edited raw data against the Thatcher Life Span Reference Data Base, (Thatcher et al, Science, Vol. 236: 1110-1113, 1987), matched for age, gender, and handedness was performed to assess functional integrity of corticocortical neural function. Data base comparisons were conducted on measures of coherence, phase, amplitude asymmetry, and relative power.

Coherence is a measure of the cross correlation of the amount of shared activity between two scalp regions. High coherence reflects a lack of differentiation, or excess similarity of cortical signal processing in brain subsystems and between regions. Low coherence reflects a lack of connection or increased differentiation of cortical signal processing in brain subsystems and between regions.

Phase is a measure of lead or lag of shared rhythms between regions measured in milliseconds. Phase in a connected system such as the cerebral cortex is a function of: EEG frequency, distance between sites, and conduction velocity. Positive phase lags suggest longer signal processing times than would be expected. Sub cortical systems as well as cortical systems may be involved.



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Amplitude Asymmetry measures amplitude differentials between interhemispheric and intra hemispheric pairs of electrodes.

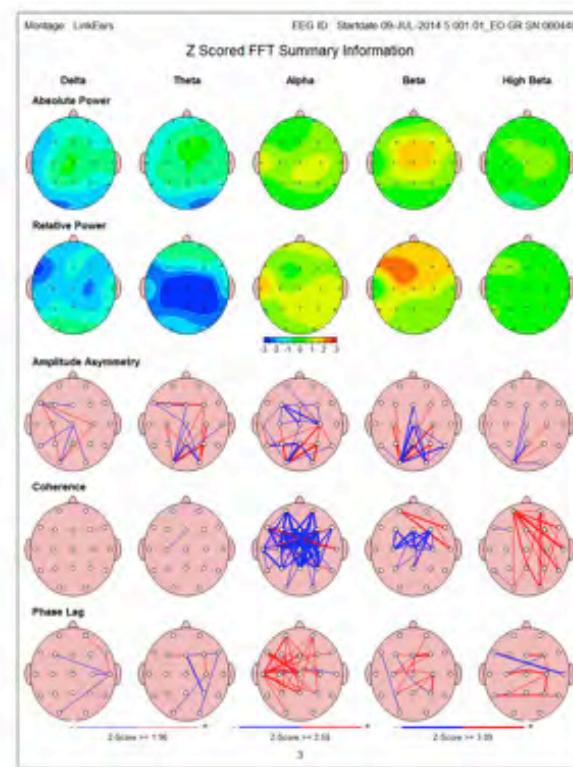
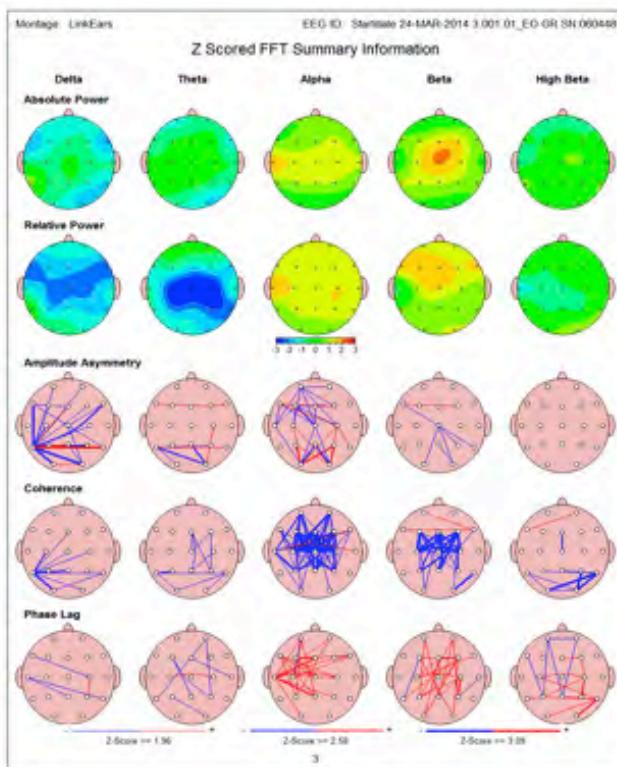
Relative Power shows the distribution of power over the cortex. All frequencies at each recording site should total 100% of power. If there is an increase in percentage power, in one frequency band other frequency bands generally decrease

RESULTS

Five of five subjects who completed the entire treatment protocol improved on all measures except the Impact Test. All pre-test QEEGs revealed statistically significant deviations from a normative data base on measures of Absolute Power, Amplitude Asymmetries, Coherence, and Phase. Post testing indicated remarkable normalization of the QEEG. The results were maintained at three-moth follow up. Summary QEEG maps are presented below. Green indicates a normal finding, yellow, orange, and red indicate excess power and a particular frequency, and light to dark blue indicate deficient power. Coherence and phase are connectivity measures with blue lines indicating hypo coherence and red lines indicating hyper coherence. Absence of lines indicates no significant deviations from normal.

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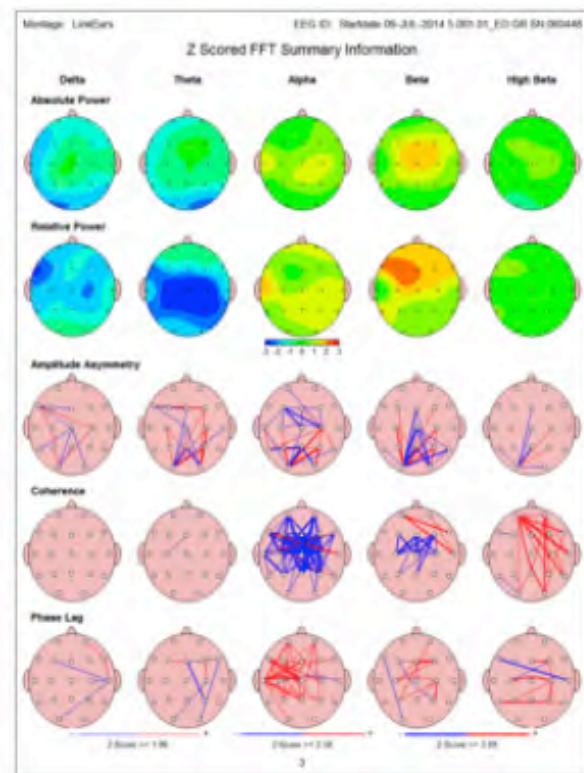
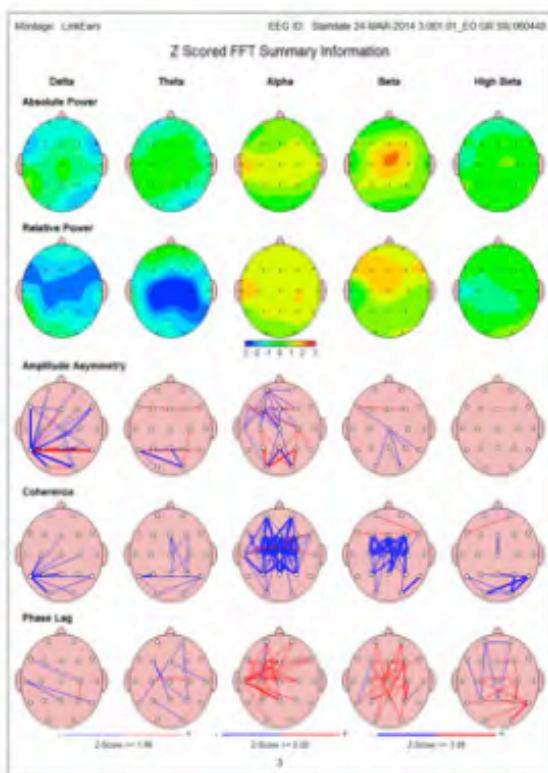
Pre and Post HPN QEEG Maps
TB01 EO Linked Ears, NFL 9 yrs.,
DB, 10 + concussions

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Pre and Post HPN QEEG Maps TB02 EO Linked Ears, NFL 8 yrs., OL, 10 + concussions

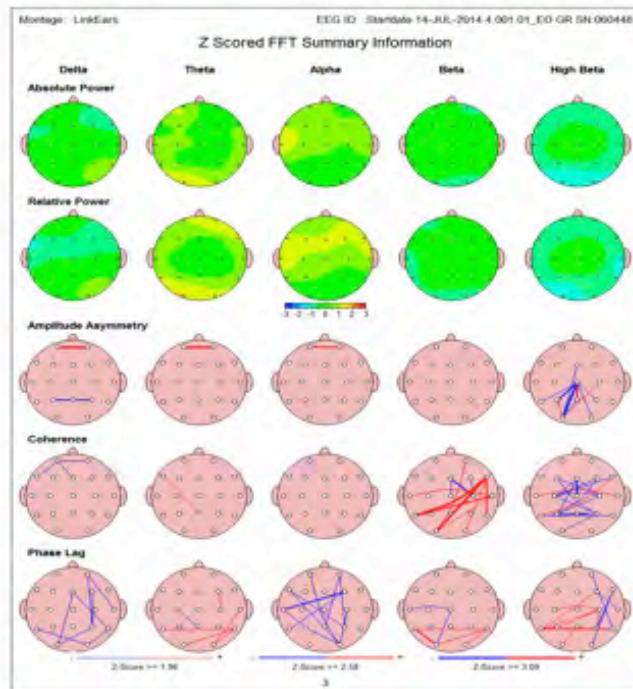
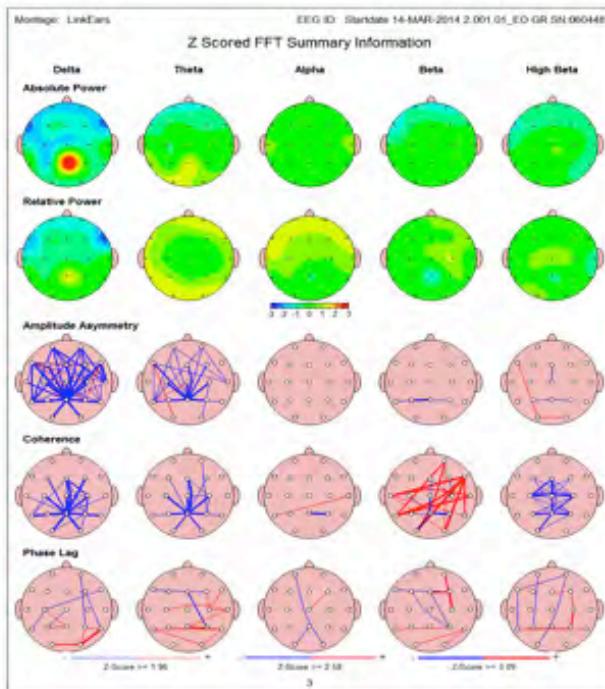


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Pre and Post HPN QEEG Maps TB02 EO Linked Ears, NFL 8 yrs., OL, 10 + concussions

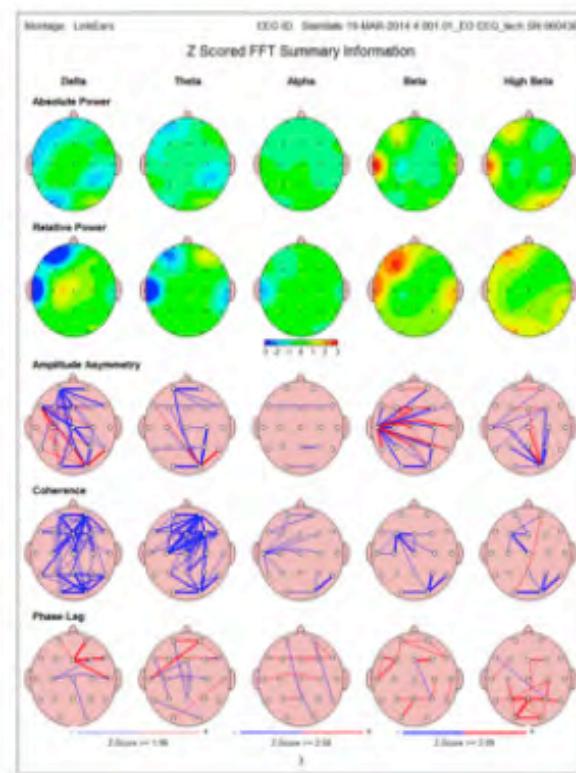
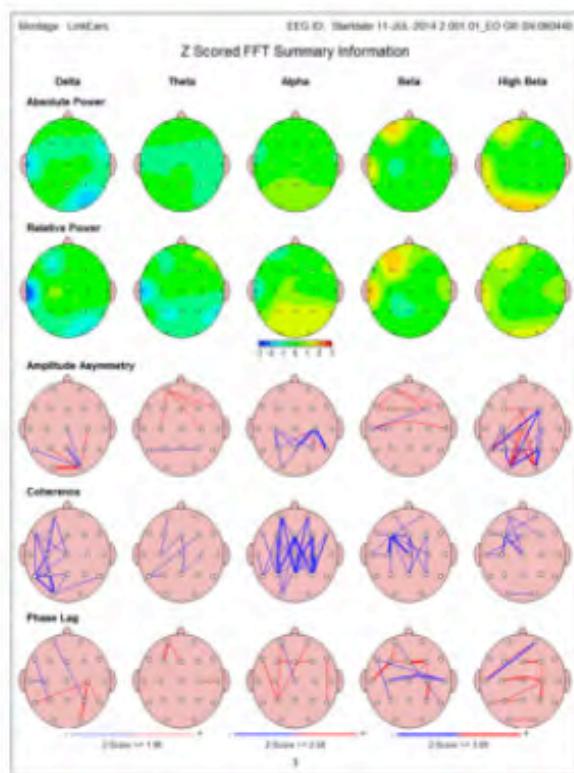


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Pre and Post HPN QEEG Maps TB03 EO Linked Ears, NFL 11 yrs., SS, 10 + concussions

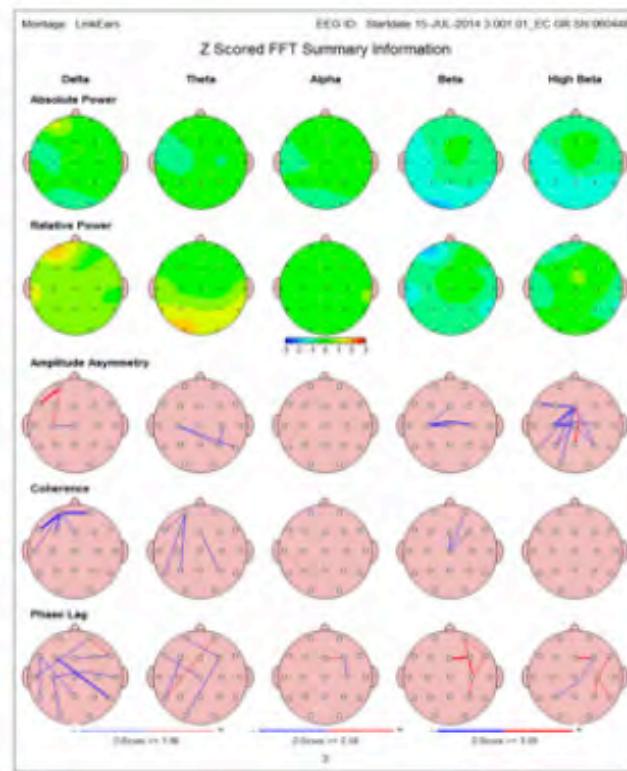
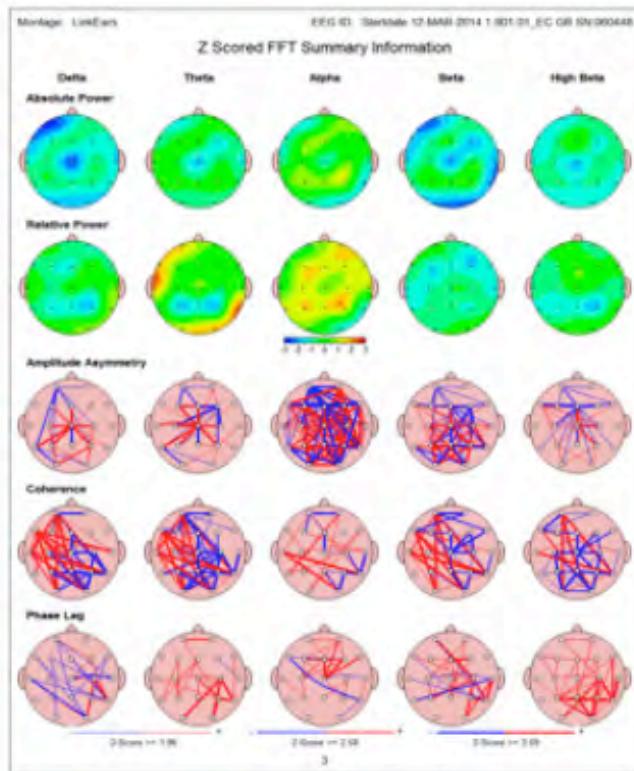


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Pre and Post HPN QEEG Maps TB04 EO Linked Ears, 11 yrs. NFL FB, 3 known concussions

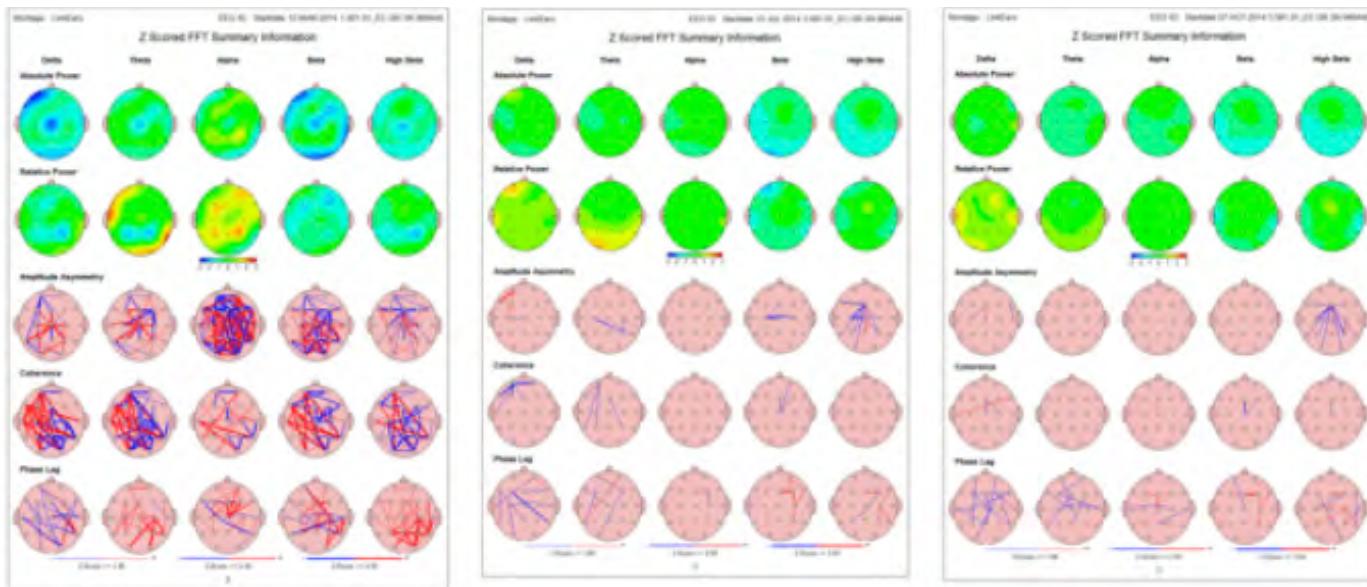


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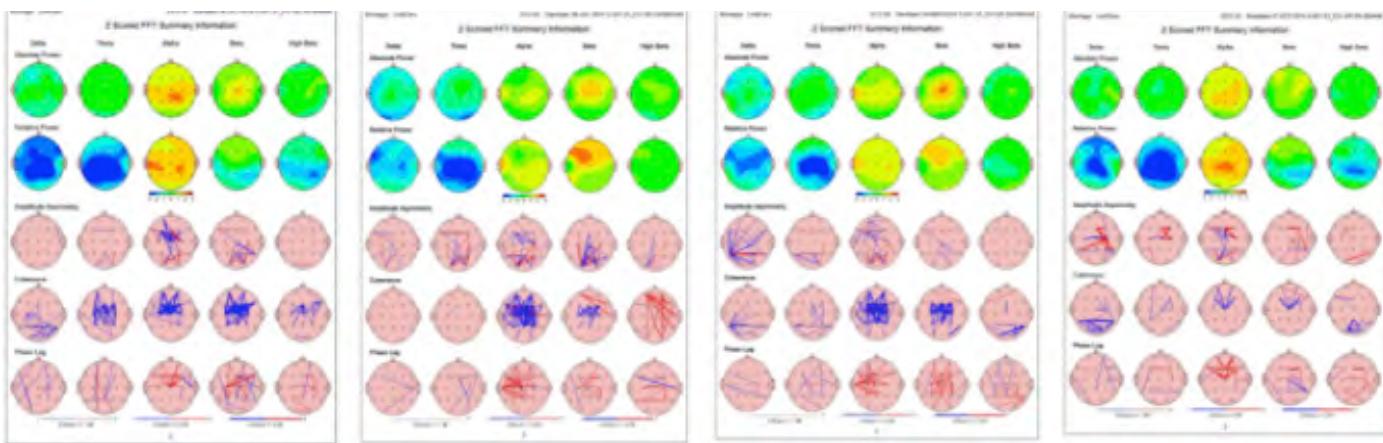


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TB04 Pre-Post 3 Month



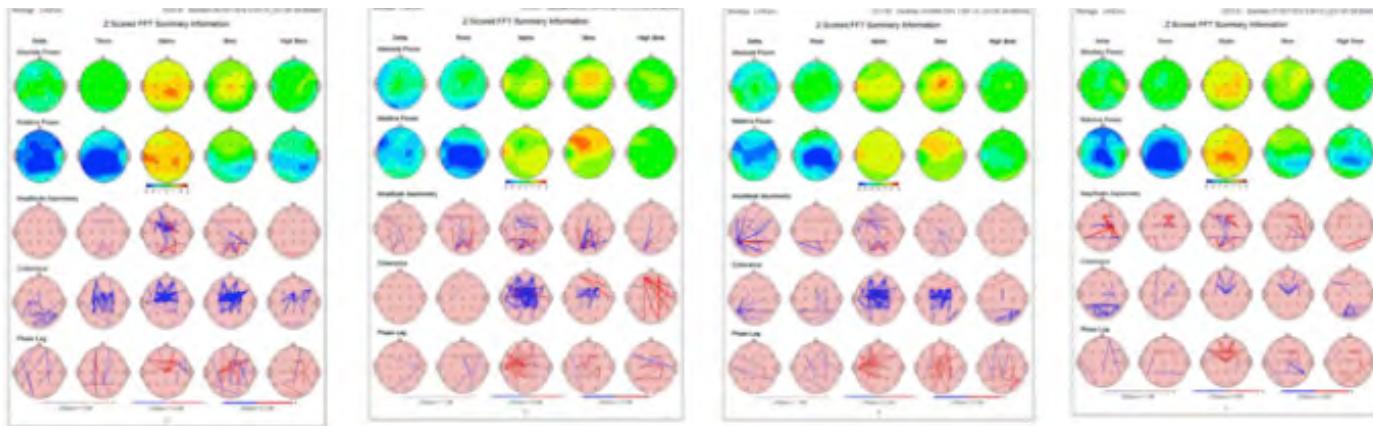
TB01 Pre-Post - 3 Month



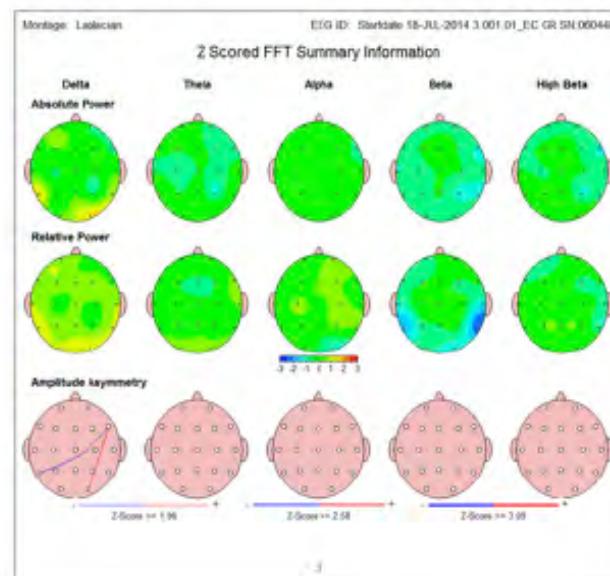
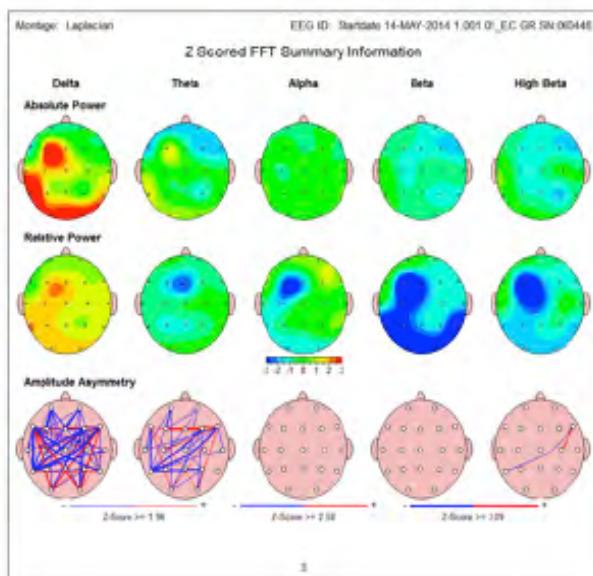


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TB01 Pre-Post - 1 Yr. Follow Up

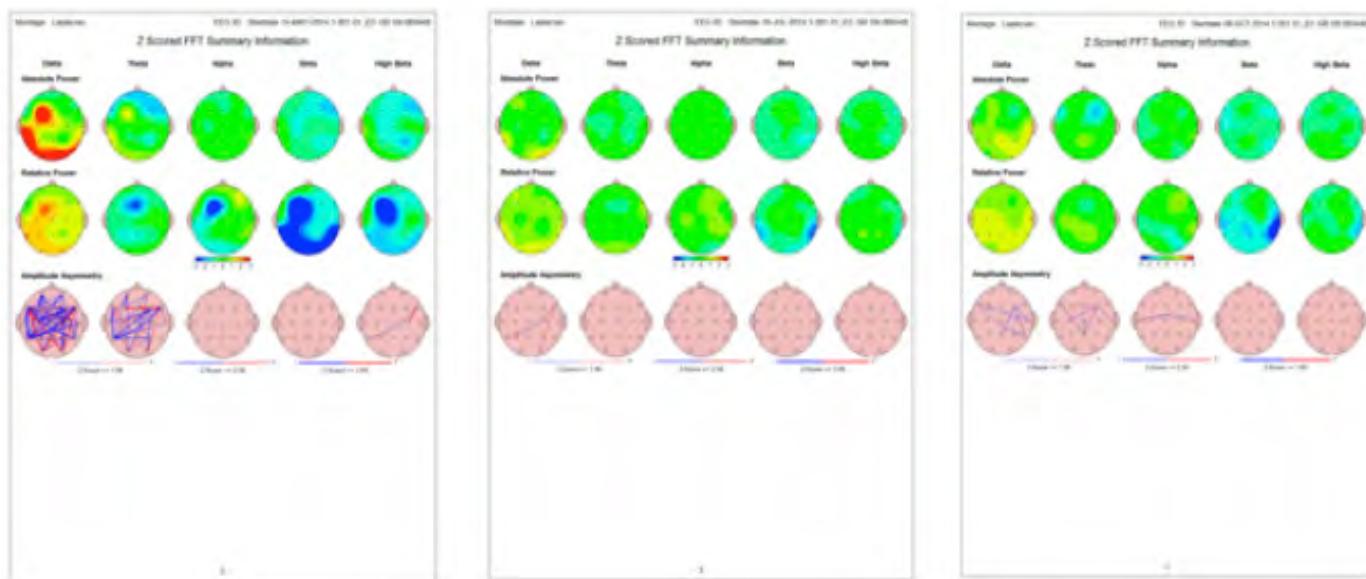
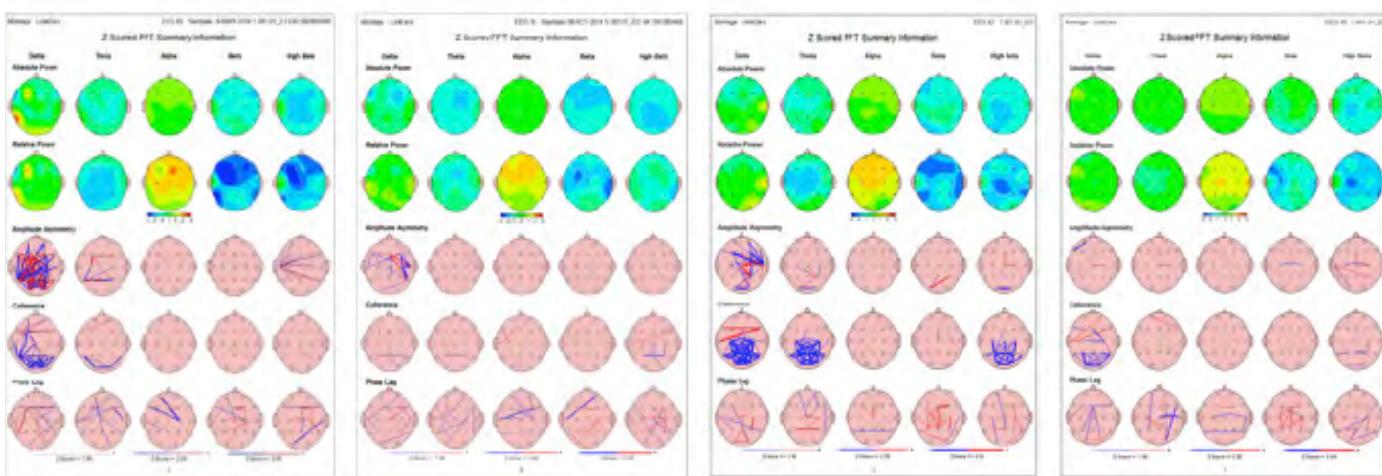


Pre and Post HPN QEEG
 TB05 EC Laplacian NFL 10 yrs.,
 2 serious concussions, 30+ dingers



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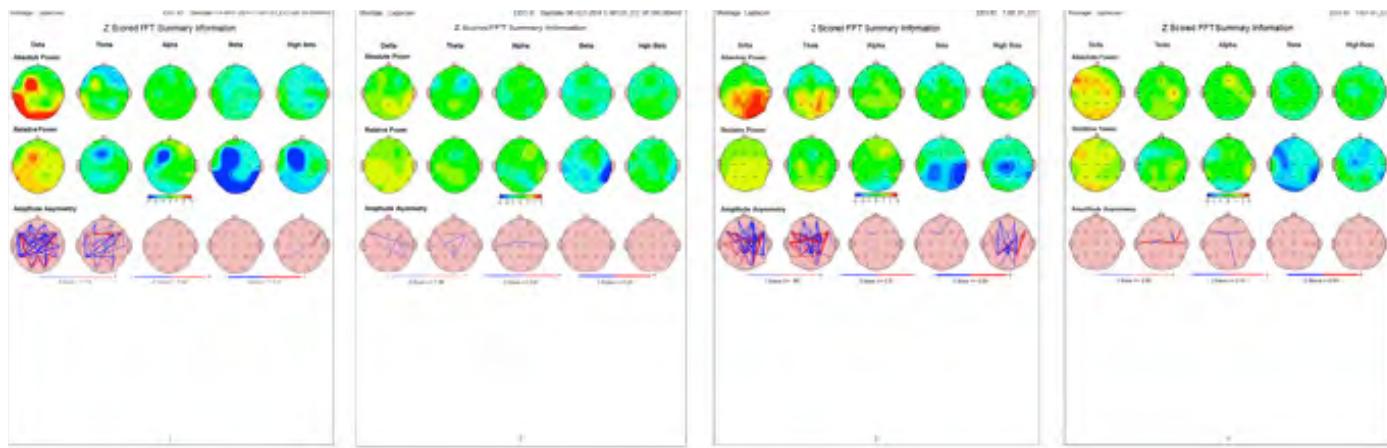
TB05 Pre-Post - 3 Month

TB05 Pre-Post - 3 Month,
Post 1Yr., Post 2 Yr. ECLE



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TB05 Pre-Post - 3 Month, Post 1 yr., Post 2 yr. ECLAP



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TB05 RIVERMEAD

The Table below indicates initial and follow up scores on the Rivermead Concussion Scale for one player from whom two-year follow-up data was obtained. Only those items initially endorsed as severe are included. The scale is 1 = no longer a problem, 2 = mild problem, 3 = moderate problem, and 4 = severe problem.

SYMPTOM	PRE-TEST	POST-TEST	3 MONTH	3 MONTH
Light Sensitivity	4	2	2	2
Insomnia	4	4	4	4
Irritability	4	1	1	1
Depression	4	1	1	1
Anxiety	4	2	2	2
Frustration	4	1	1	1
Forgetfulness	4	2	2	2
Concentration	4	1	1	1
Impulsiveness	4	1	1	1
SYMPTOM	36	15	16	19

OBSERVATION & CONCLUSION

The devastating effects of repetitive brain trauma are reflected in cognitive, emotional, and behavioral dysregulation. Psychological changes (depression and suicidal thoughts) and cognitive impairments (confusion and memory loss) can also lead to lack of impulse control and domestic violence.

Most research to date has focused on identifying the end result of CTE in autopsied brains. The relationship between rTBI and CTE is being better understood. Increased awareness has led to some rules changes, better equipment design, implementation of concussion protocols, and players making the decision to retire earlier in their careers. The concern about concussions has trickled down to youth sports with many parents pulling their kids from contact sports. However, it is the nature of the game that concussive injuries will continue to occur. There remains a need for effective treatment interventions.



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This pilot study provides evidence that HPN can be a viable treatment approach. Follow up reports also suggest that there may be a tendency to back slide in some areas. It is not clear if the treatment has any effect on the aggregation of tau protein in the brain. Symptom resolution does not necessarily mean the disease progression has stopped. Until reliable biomarkers of CTE in a living brain are readily available this question will remain. Some players have chosen to continue with periodic maintenance treatments because they have gained an awareness of subtle changes in their cognition or behavior.

It is clear that rTBI can be complex with ramifications for physical health, psychological health, behavioral health, and family relationships. For this reason, a more comprehensive multi-modal approach offers the best chance of sustained recovery. HPN appears to be a suitable treatment that could reverse the effects of brain injuries like rTBI and should be considered as part of a comprehensive concussion management program.

While the results are encouraging, they need to be replicated in a larger controlled study by independent researchers. Such an effort is currently underway with the intention of publishing results and advancing the field.

CTE is a neurodegenerative disease that occurs after exposure to repetitive head trauma. Cumulative exposure to trauma, not the number of concussions, is associated with the severity of p-tau pathology, suggesting that sub concussive impacts are important for disease development.

CTE most commonly manifests in midlife and produces clinical symptoms of disordered cognition, memory loss, executive dysfunction, depression, apathy, disinhibition, and irritability as well as Parkinsonism. The neuropathology of CTE is increasingly well defined; a NINDS/NIBIB panel of expert neuropathologists has identified preliminary criteria and a pathognomonic lesion for the neuropathological diagnosis of CTE. Currently, neuropathological examination of postmortem brain tissue is the only way to diagnose CTE, although intense research efforts are under way to identify biomarkers to detect and monitor the disease during life and to develop therapies such as HPN High Performance Neurofeedback to slow or reverse its course.

SUMMARY CONCLUSION

- HPN is an effective treatment for NFL players
- NFL players are hard to reach and they tend to be skeptical.
- It is important to give them a treatment in which they can feel a difference after first session.
- They may also be dealing with chronic pain, liver and kidney issues, addiction to prescription and non-prescription drugs, other medical conditions, and an attorney who is advising them to not get treatment.
- More controlled research and corroboration is needed.
- Many will need a more comprehensive approach